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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Patent of:	**REQUEST FOR CERTIFICATE OF CORRECTION OF PATENT FOR PTO MISTAKE (37 C.F.R. 1.322(a))**
RANTALA et al.	
Patent No.: 6,912,413 B2	
Issued: June 28, 2005	CERTIFICATE OF MAILING I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450 ON 7/1/05 MARSH FISCHMANN & BREYFOGLE LLP BY: Dolene Rey
Confirmation No.: 6801	
Atty. File No.: 44565-00041	
For: "PULSE OXIMETER"	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Certificate
JUL 1 1 2005
of Correction

Dear Sir:

This is a request for a Certificate of Correction for PTO mistake under 37 C.F.R. 1.322(a). The errors in the patent are obvious typographical errors or omissions and the correct wording can be found in the original specification at Page 2, line 10, or the Amendment and Response dated November 29, 2004, at Page 4, line 5. Attached is form PTO 1050 in duplicate along with copies of documentation that unequivocally supports patentee's assertion(s).

Respectfully submitted,

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Date: 7/1/05

JUL 1 1 2005

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,912,413 B2
DATED : June 28, 2005
INVENTOR(S): RANTALA et al.

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 2
Line 1, delete "carboxyhemogiobin" and insert therefor --carboxyhemoglobin--.

Column 9
Line 2, delete "transfoming", and insert therefor --transforming--.

MAILING ADDRESS OF SENDER:
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PATENT NO. 6,912,413 B2

hemoglobin, oxyhemoglobin (HbO_2), and deoxyhemoglobin (RHb), absorption must be measured at two different wavelengths, i.e. the probe includes two different light emitting diodes (LEDs). The wavelength values widely used are 660 nm (red) and 940 nm (infrared), since the said two species of hemoglobin have substantially different absorption values at these wavelengths. Each LED is illuminated in turn at a frequency which is typically several hundred Hz.

The accuracy of a pulse oximeter is affected by several factors. This is discussed briefly in the following.

Firstly, the dyshemoglobins which do not participate in oxygen transport, i.e. methemoglobin (MetHb) and carboxyhemoglobin (CoHb), absorb light at the wavelengths used in the measurement. Pulse oximeters are set up to measure oxygen saturation on the assumption that the patient's blood composition is the same as that of a healthy, non-smoking individual. Therefore, if these species of hemoglobin are present in higher concentrations than normal, a pulse oximeter may display erroneous data.

Secondly, intravenous dyes used for diagnostic purposes may cause considerable deviation in pulse oximeter readings. However, the effect of these dyes is short-lived since the liver purifies blood efficiently.

Thirdly, coatings such as nail polish may in practice impair the accuracy of a pulse oximeter, even though the absorption caused by them is constant, not pulsátile, and thus in theory it should not have any effect on the accuracy.

Fourthly, the optical signal may be degraded by both noise and motion artifacts. One source of noise is the ambient light received by the photodetector. Many solutions have been devised with the aim of minimizing or eliminating the effect of the movement of the patient on the signal, and the ability of a pulse oximeter to function correctly in the presence of patient motion depends on the design of the pulse oximeter. One way of canceling out the motion artifact is to use an extra wavelength for this purpose.

One of the current trends in pulse oximetry is the aim towards lower power consumption, which is essential for battery-operated oximeters, for example. These oximeters are typically mobile and must therefore be used in various locations where both the characteristics of the patient and the surrounding measurement environment may vary. A problem related to these various measurement conditions is the optimization of power consumption without compromising the performance of the device, i.e. how to guarantee reliable measurement results even in difficult measurement conditions and still

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	) Group Art Unit: 3736
RANTALA	) Examiner: KREMER, MATTHEW
Serial No.: 10/661,012	) AMENDMENT AND RESPONSE
Filed: September 12, 2003	)
Confirmation No.: 6801	)
Atty. File No.: 44565-00041	)
For: "PULSE OXIMETER"	)

CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450 ON [illegible]

MARSH FISCHMANN & BREYFOGLE, LLP

BY [signature]

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant submits this Amendment and Response to address the Office Action having a mailing date of June 29, 2004. Enclosed herewith is a petition for two-month extension of time, thereby extending the time period for response from September 29, 2004 to November 29, 2004. Also enclosed is a check in the amount of $734.00 including $430.00 as the fee for the extension and $304.00 as the fee for the additional claims presented herein. Please credit any overpayment or charge any underpayment to Deposit Account No. 50-1419.

Please amend the above-identified patent application as follows:

IN THE CLAIMS:

1. (Currently Amended) A method for controlling optical power in a monitoring device intended for determining the amount of at least one light absorbing substance in a subject, the monitoring device comprising

-emitters for emitting radiation at a minimum of two wavelengths

-driving means for activating said emitters, and

-a detector for receiving said radiation at said wavelengths and for producing an electrical signal in response to the radiation,

the method comprising the steps of

-supplying driving pulses from said driving means to the emitters, the pulses having predetermined characteristics determining the optical power of the device,

-demodulating the electrical signal originating from said detector whereby a baseband signal is obtained;

transforming the baseband signal into a frequency spectrum to identify an amplitude and a noise level of the baseband signal, whereby a signal-to-noise ratio of the amplitude to the noise for the baseband signal is obtained;

-monitoring ~~a~~ the signal-to-noise ratio of the baseband signal, and

-controlling the duty cycle of the driving pulses in dependence on the monitored signal-to-noise ratio.

2. (Currently Amended) A method according to claim 1, wherein said controlling step includes controlling the duty cycle of the driving pulses so that the ~~optical power~~ signal to noise ratio is ~~minimized~~ maintained within the confines of a predetermined ~~lower threshold set~~range for the signal-to-noise ratio.

3. (Currently Amended) A method according to claim 2, wherein said controlling step further includes comparing the monitored signal-to-noise ratio to said predetermined range, said predetermined range being defined by a predetermined lower threshold and ~~to~~ a predetermined higher threshold.

4. (Original) A method according to claim 3, further including the step of connecting the electrical signal originating from said detector through a preamplifier and a low-pass-filter prior to said demodulating step.

5. (Original) A method according to claim 4, wherein said controlling step includes

-performing at least one operation in response to said signal-to-noise ratio reaching said lower threshold, the said at least one operation being selected from a group of operations including (1) the increase of the width of said pulses and (2) the increase of pulse repetition rate, and

- decreasing the bandwidth of said low-pass filter when the width of said pulses is increased.

6. (Original) A method according to claim 5, wherein the controlling step further includes the step of increasing the amplitude of said driving pulses.

7. (Original) A method according to claim 4, wherein said controlling step includes

-selecting at least one operation in response to said signal-to-noise ratio reaching said higher threshold, the said at least one operation being selected from a group of operations including (1) the decrease of the width of said pulses and (2) the decrease of pulse repetition rate, and

- increasing the bandwidth of said low-pass filter when the width of said pulses is decreased.

8. (Original) A method according to claim 8, wherein the controlling step further includes the step of decreasing the amplitude of said driving pulses.

9. (Original) A method according to claim 1, wherein said demodulating step includes sampling of the electrical signal by a synchronous detector, taking one sample per each pulse of the electrical signal.

10. (Original) A method according to claim 1, wherein the amount of at least one light absorbing substance is determined in the blood of a subject.

11. (Original) A method according to claim 1, wherein the monitoring device is a pulse oximeter.

12. (Currently Amended) An apparatus for non-invasively determining the amount of at least one light absorbing substance in a subject, the apparatus comprising

- emitters for emitting radiation at a minimum of two different wavelengths,

- driving means for activating said emitters, adapted to supply driving pulses to the emitters, the pulses having predetermined characteristics determining current optical power of the device,

- a detector for receiving said radiation at said wavelengths an producing an electrical

signal in response to the radiation,

- a demodulator unit for demodulating the electrical signal originating from the detector, whereby a baseband signal is obtained from the demodulator unit,

- monitoring means for:

transforming the baseband signal into a frequency spectrum;

generating a signal-to-noise ratio of the transformed baseband signal; and

monitoring the signal-to-noise ratio of the baseband signal, and

- power control means, responsive to the monitoring means, for controlling the duty cycle of the driving pulses.

13. (Currently Amended) An apparatus according to claim 12, wherein the power control means are adapted to control the duty cycle so that the ~~optical power is minimized within the confines of a predetermined lower threshold set for the~~ signal-to-noise ratio is maintained within a predetermined range between a first threshold and a second threshold.

14. (Original) An apparatus according to claim 13, further comprising a low-pass filter for filtering said electrical signal prior to said demodulating, the control means comprising at least one set of first and second means, wherein the first means are adapted to change the width of said pulses and of the passband of the low-pass filter, and the second means are adapted to increase pulse repetition rate.

15. (Original) An apparatus according to claim 14, wherein the control means further comprise means for changing the amplitude of said pulses.

16. (Currently Amended) An apparatus according to claim 13, wherein said apparatus ~~being a non-invasive monitoring device, preferably~~ is a pulse oximeter.

17. (New) A method for controlling optical power in a monitoring device intended for determining the amount of at least one light absorbing substance in a subject, the monitoring device comprising

-emitters for emitting radiation at a minimum of two wavelengths,

-driving means for activating said emitters, and

-a detector for receiving said radiation at said wavelengths and for producing an electrical signal in response to the radiation,

the method comprising the steps of

-supplying driving pulses from said driving means to the emitters, the pulses having

predetermined characteristics determining the optical power of the device,

-demodulating the electrical signal originating from said detector to generate demodulated signals for said wavelengths;

- obtaining a DC signal component for at least one of said demodulated signals;

-monitoring a signal-to-noise ratio of the DC signal component, and

-controlling the duty cycle of the driving pulses in dependence on the monitored signal-to-noise ratio of the DC signal component.

18. (New) A method according to claim 17, wherein said controlling step includes controlling the duty cycle of the driving pulses so that the signal to noise ratio is maintained within the confines of a predetermined range for the signal-to-noise ratio.

19. (New) A method according to claim 18, wherein said controlling step further includes comparing the monitored signal-to-noise ratio to said predetermined range, said predetermined range being defined by a predetermined lower threshold and a predetermined higher threshold.

20. (New) A method according to claim 19, further including the step of connecting the electrical signal originating from said detector through a preamplifier and a low-pass-filter prior to said demodulating step.

21. (New) A method according to claim 20, wherein said controlling step includes

-performing at least one operation in response to said signal-to-noise ratio reaching said lower threshold, the said at least one operation being selected from a group of operations including (1) the increase of the width of said pulses and (2) the increase of pulse repetition rate, and

- decreasing the bandwidth of said low-pass filter when the width of said pulses is increased.

22. (New) A method according to claim 21, wherein the controlling step further includes the step of increasing the amplitude of said driving pulses.

23. (New) A method according to claim 20, wherein said controlling step includes

-selecting at least one operation in response to said signal-to-noise ratio reaching said higher threshold, the said at least one operation being selected from a group of operations including (1) the decrease of the width of said pulses and (2) the decrease of pulse repetition rate, and

- increasing the bandwidth of said low-pass filter when the width of said pulses is

decreased.

24. (New) A method according to claim 23, wherein the controlling step further includes the step of decreasing the amplitude of said driving pulses.

25. (New) A method according to claim 17, wherein said demodulating step includes sampling of the electrical signal by a synchronous detector, taking one sample per each pulse of the electrical signal.

26. (New) A method according to claim 17, wherein the amount of at least one light absorbing substance is determined in the blood of a subject.

27. (New) A method according to claim 17, wherein the monitoring device is a pulse oximeter.

28. (New) An apparatus for non-invasively determining the amount of at least one light absorbing substance in a subject, the apparatus comprising

- emitters for emitting radiation at a minimum of two different wavelengths,

- driving means for activating said emitters, adapted to supply driving pulses to the emitters, the pulses having predetermined characteristics determining current optical power of the device,

- a detector for receiving said radiation at said wavelengths an producing an electrical signal in response to the radiation,

- a demodulator unit for demodulating the electrical signal originating from the detector to generate demodulated signals for said wavelengths, whereby a DC signal component of at least one of said demodulated signals is obtained from the demodulator unit,

- monitoring means for monitoring a signal-to-noise ratio of the DC signal component, and

- power control means, responsive to the monitoring means, for controlling the duty cycle of the driving pulses.

29. (New) An apparatus according to claim 28, wherein the power control means are adapted to control the duty cycle so that the signal-to-noise ratio is maintained within a predetermined range between a first threshold and a second threshold.

30. (New) An apparatus according to claim 29, further comprising a low-pass filter for filtering said electrical signal prior to said demodulating, the control means comprising at least one set of first and second means, wherein the first means are adapted to change the width of said

pulses and of the passband of the low-pass filter, and the second means are adapted to increase pulse repetition rate.

31. (New) An apparatus according to claim 30, wherein the control means further comprise means for changing the amplitude of said pulses.

32. (New) An apparatus according to claim 29, wherein said apparatus is a pulse oximeter.

REMARKS

This application has been carefully reviewed in light of the Examiner's action dated June 29, 2004. Claims 1, 12 and 16 have been amended and claims 17-32 have been added. Reconsideration and full allowance are respectfully requested.

Claims 1-3, 10-13 and 16 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication 2004/0002637 to Huang et al (hereafter Huang II). As set forth below, all the claims are believed to be allowable as presented and therefore, this rejection is respectfully traversed. The noted claims include independent claims 1 and 12.

As presented, independent claim 1 is directed to a method for controlling optical power in a monitoring device in manner that reduces power consumption without compromising the performance of the device. The method is performed in a monitoring device that is intended for use in determining the amount of at least one light absorbing substance in subject. The device includes emitters for emitting radiation at a minimum of two wavelengths, driving means for activating the emitters and a detector for receiving the radiation at the wavelengths and producing an electrical response to the received radiation. The method includes the steps of supplying driving pulses to the emitters, which have predetermined characteristics that determine the optical power of the device, and demodulating the electrical signal originating from the detector to obtain a baseband signal. The baseband signal is transformed into a frequency spectrum to identify an amplitude and noise level for the baseband signal. The amplitude and noise level are then utilized to obtain a signal-to-noise ratio for the baseband signal. Finally, the method includes monitoring the signal-to-noise ratio of the baseband signal and controlling the duty cycle of the driving pulses in dependence on the monitored signal-to-noise ratio.

Independent claim 12 is directed to an apparatus for noninvasively determining the amount of at least one light absorbing substance in a subject. The apparatus includes emitters for emitting radiation and at a minimum of two different wavelengths and driving means for activating the emitters, wherein the driving means is adapted to supply driving pulses to the emitters that have predetermined characteristics that determine that optical power of the device. The apparatus also includes a detector for receiving radiation from the emitters and producing an electrical signal in response to the received radiation. The apparatus also includes a demodulator unit for demodulating the electrical signal from the detector to obtain a baseband signal. The apparatus further includes a

monitoring means for transforming the baseband signal to a frequency spectrum, generating a signal-to-noise ratio of the transformed baseband signal and monitoring that signal-to-noise ratio. Finally, the apparatus includes a power control means that is responsive to the monitoring means for controlling the duty cycle of the driving pulses.

In both the method and apparatus, a baseband signal, e.g. a "DC component", of the received radiation is obtained. This baseband is then transformed into a frequency spectrum such that a signal-to-noise ratio of the baseband may be identified. This signal-to-noise ratio is in monitored such that the duty cycle of the driving pulses, which are utilized drive the emitters, may be varied such that the total power consumption of the device may be reduced without compromising the performance of the device.

Initially, the applicant notes that the present application has a filing date of September 12, 2003 and claims priority to U.S. Provisional Application No. 60/410,526 having a filing date of September 13, 2002. The disclosure of the Provisional Application 60/410,526 and the present application are identical. The Applicant further notes that Huang II is a 102(e) reference having a filing date of March 10, 2003 and claims priority to U.S. Provisional Application No. 60/363,791 (Huang I), which has a filing date of March 12, 2002. Accordingly, only the disclosure of Huang I is prior art to the present application.

Huang I is directed to a pulse oximeter that minimizes the brightness of LED emitters in order to conserve power. Accordingly, Huang I fails to disclose or suggest the method and/or apparatus set forth in relation to independent claims 1 and 12. For instance, Huang I fails to disclose or suggest, inter alia, altering the duty cycle of driving pulses supplied to emitters of a device for determining the amount of at least one light absorbing substance in subject. Further, Huang I fails to disclose transforming a detector signal into a frequency spectrum in order to determine a signal-to-noise ratio of that signal. Additionally, Huang I fails to disclose the use of the baseband portion of a detector signal for determination of a signal-to-noise ratio. In fact, Huang II teaches away from the use of the baseband or DC component of a detector signal in order to identify a signal characteristic of interest (e.g., signal-to-noise ratio). Specifically, Huang II provides:

> The received signal characteristics of interest in the Modulated Signal 26 and corresponding Received Signal 30 will include a steady state or time invariant, or "dc", component, such as a component due to the steady state volume of blood in a tissue or organ, a time varying or "ac" component indicative of the varying volume of blood flowing through the tissue or organ, and a "noise" component arising from

> various sources. The information sought to be extracted from the Modulated Signal 26 and Received Signal 30 for generating a Parameter Output 34 representing the oxygen saturation levels of blood in a body organ or tissues is thereby primarily the "ac" component of the signal, which is indicative of the varying volume of blood flowing through the tissue or organ. As such, either or both of the "dc" and "noise" components are either of less interest for these purposes or may interfere with the extraction of the information of interest. The amplitude or signal strength of the "ac" component is thereby representative of the Parameter 24, that is, the oxygen saturation level, while the ratio of the amplitude of the "ac" component relative to other signal components, that is, the signal to noise ratio of the "ac" component, is pertinent to the "quality" of the Modulated Signal 26 and Received Signal 30. Page 5, Paragraph 38.

Accordingly, for these reasons Applicant respectfully requests that the rejections based on Huang to Independent Claims 1 and 12 be withdrawn.

The examiner also rejected the dependent claims 4 and 9 under 35 U.S.C. 103(a) as being unpatentable under Huang II in view of various combinations and of U.S. Patent Nos. 5,348,004 to Hollub, 4,856,057 to Taylor et al., and 6,714,803 to Mortz. Applicant respectfully submits these claims each depend from an allowable base claim (independent claim 1) and are therefore allowable for the reasons set forth above. Accordingly, applicant requests that this rejection be withdrawn.

Claims 1, 10-12 and 16 were also rejected under 35 U.S.C. §103(a) as being unpatenable over U.S. Patent No. 6,731,967 to Turcott in view of U.S. Patent No. 6,356,774 to Bernstein et al.. As set forth below, all the claims are believed to be allowable as presented and therefore, this rejection is respectfully traversed.

As noted above, claims 1 and 12 are directed to a method and apparatus for controlling optical power in a monitoring device in manner that reduces power consumption without compromising the performance of the device. More specifically, emitters emit radiation at a minimum of two wavelengths as determined by a driving means that activate the emitters and a detector receives the radiation and produces an electrical signal in response to the received radiation. The electrical signal is demodulated and a baseband signal, e.g. a "DC component", of the electrical signal is obtained. This baseband signal is then transformed into a frequency spectrum such that a signal-to-noise ratio of the baseband signal may be identified. The signal-to-noise ratio is then monitored such that the duty cycle of the driving pulses, which are utilized drive the emitters, may be varied to reduce the total power consumption of the monitoring device.

Turcott is directed a system and method for providing a relatively constant average light intensity at light detector of a plethysmographic device. Col. 5 line 65 - Col. 6 line 6. In this regard, movement of detected light intensity of from a set point induces and increase or decrease of source intensity. "Specifically, if the detected light moves above (i.e., higher than) the set point, then the source intensity is decreased." Col. 6 lines 13-15. Such a system purportedly reduces power consumption of the device. Col. 2 lines 53- 57. As presented, Turcott utilizes a detector output signal that is indicative of the light intensity received by the detector as a feedback signal (Col. 15 lines 50-55) for adjusting source intensity. However, Turcott fails to disclose or suggest, inter alia, isolation of a baseband signal from a detector signal or use of the baseband signal to obtain a signal-to-noise ratio. As Turcott fails to isolate a baseband signal, Turcott unsurprisingly fails to disclose or suggest transforming such a baseband signal into a frequency spectrum to calculate such a signal-to-noise ratio. Likewise, Turcott fails to disclose monitoring a signal-to-noise ratio for use in adjusting the duty cycle of driving pulses supplied to emitters.

Bernstein fails to overcome the shortcomings of Turcott. As presented, Bernstein is directed to a method for operating a light emitter of an oximeter sensor at its maximum allowable intensity without burning a patient. See Abstract. In this regard, a temperature-dependent electrical characteristic is encoded into the sensor. The encoded temperature-dependent electrical characteristic may be read and utilize modify the driving of the light emitter in the sensor. This purportedly allows a light emitter to be operated its maximum allowable intensity to maximize a signal-to-noise ratio, without burning a patient. Col 2 line 59 – Col 3 line 4. However, Bernstein fails to disclose or suggest isolating a baseband signal, e.g. a "DC component", of a detector signal, transforming the baseband signal into a frequency spectrum in order to determine a signal-to-noise ratio, or, monitoring the signal-to-noise ratio to vary the duty cycle of driving pulses supplied to emitters.

Applicant submits that the proposed combination of Turcott and Bernstein would not produce the claimed subject matter of claims 1 and 12. Specifically, neither cited reference disclose obtaining a baseband signal (e.g., DC component) from a detector output and/or transforming a signal into a frequency spectrum in order to obtain a signal-to-noise ratio for that signal. In addition to the noted shortcomings, applicant further submits a combination of Turcott and Bernstein is improper as Bernstein is directed to a system and method for maximizing source intensity whereas Turcott is at least partially directed to system and method for allowing power consumption to be minimized. Col.

2 lines 53 - 57. Stated otherwise, Bernstein teaches away from Turcott. Accordingly, there is simply no motivation for one skilled in the art to make the combination suggested by the examiner. Accordingly, applicant submits that independent claims 1 and 12 are allowable as presented.

Based upon the foregoing, Applicants believe that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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Date: November 29, 2004